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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,290	08/21/2001	Rosana Kapeller-Libermann	MNI-186	8801

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Intellectual Property Group
MILLENNIUM PHARMACEUTICALS INC.
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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Advisory Action After the Filing of an Appeal Brief	Application No. 09/935,290	Applicant(s) KAPELLER-LIBERMANN ET AL.	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The reply filed 18 February 2005 is acknowledged.

1. ☐ The reply filed on or after the date of filing of an appeal brief, but prior to a final decision by the Board of Patent Appeals and Interferences, will not be entered because:

   a. ☐ The amendment is not limited to canceling claims (where the cancellation does not affect the scope of any other pending claims) or rewriting dependent claims into independent form (no limitation of a dependent claim can be excluded in rewriting that claim). See 37 CFR 41.33(b) and (c).

   b. ☐ The affidavit or other evidence is not timely filed before the filing of an appeal brief. See 37 CFR 41.33(d)(2).

2. ☐ The reply is not entered because it was not filed within the two month time period set forth in 37 CFR 41.39(b), 41.50(a)(2), or 41.50(b) (whichever is appropriate). Extensions of time under 37 CFR 1.136(a) are not available.

   Note: This paragraph is for a reply filed in response to one of the following: (a) an examiner's answer that includes a new ground of rejection (37 CFR 41.39(a)(2)); (b) a supplemental examiner's answer written in response to a remand by the Board of Patent Appeals and Interferences (37 CFR 41.50(a)(2)); or (c) a Board of Patent Appeals and Interferences decision that includes a new ground of rejection (37 CFR 41.50(b)).

3. ☒ The reply is entered. An explanation of the status of the claims after entry is below or attached.

4. ☐ Other: _____

The after-final amendment filed February 18, 2005 will be entered, when an appeal brief is filed. Upon entry of the amendment, claims 6-8 will be amended, claim 4 will be cancelled, and claims 1, 2, and 6-11 will be in the case.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 6-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported for the reasons set forth in the prior Office actions mailed January 21, 2004 and September 15, 2004.

Claims 1, 2, and 6-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the nucleic acid sequence of SEQ ID NO: 1 or 3, and the protein of SEQ ID NO: 2.

In response to the above rejection, applicants continue to argue that the specification sets forth use of the described compositions in methods of use as well as methods for diagnostics and identification of therapeutics for disorders including, and that one of ordinary skill in the art would have recognized well-established utility.

Applicants' arguments filed February 18, 2005 have been fully considered, but they are found unpersuasive. Indeed, the specification sets forth an asserted utility for the polypeptide of SEQ ID NO: 2, i.e., an acyltransferase activity, but the specification fails to identify a specific or substantial utility for said acytransferase. Acyltransferase activity requires at least two substrates one of which an acyl donor and the other an acyl aceptor. Neither the acyl donor nor acceptor is identified in the specification. No acyl-transferase activity of any kind is demonstrated in the specification. Also, the specification fails to identify any specific metabolic pathway in which the nucleic acid of SEQ ID NO: 1 or 3, or the polypeptide of SEQ ID NO: 2 are involved. No specific disease or syndrome is shown to be related to abnormality in the activity or expression

of said polypeptide. Thus, one of ordinary skill in the art would not be able to identify any specific real world utility after reading the specification.

Applicants have contended that the examiner has not established *prima facie* case of lack of utility as required by MPEP 2107 (II)(C). The examiner disagrees and refers the applicants to review the Office action mailed January 21, 2004. Also, applicants are invited to review their own specification and identify a single specific or substantial utility, which the examiner may have missed. Applicants point specifically to page 10 of the specification as containing number of utilities. The examiner reviewed page 10 in its entirety could not identify any specific or substantial utility, and found it as a mere wish list of things that could be done with the nucleic acid and polypeptide. Page 10 in its entirety is a *prima facie* evidence of lack of specific or substantial utility at the time the application was filed. Applicants' argument that acyltransferases have well-established utility in the prior art and therefore, one of ordinary skill in the art knows its utility was considered and addressed. In the Office action mailed January 21, 2004, it was indicated that acyl transferases are family of enzymes having diverse biological functions and chemical specificity. Since the acyltransferase of SEQ ID NO: 2 appears to be novel, one of ordinary skill in the art would not know its biological function or chemical specificity, and thus, would not know a specific or substantial utility for it. The definition of specific and substantial utilities are stated in the MPEP 2107 (I):

"Specific Utility

A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. Knapp v. Anderson, 477 F.2d 588, 177 USPQ 688 (CCPA 1973)."

and

"Substantial Utility

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;

(B) A method of treating an unspecified disease or condition;

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;

(D) A method of making a material that itself has no specific, substantial, and credible utility; and

(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. See, e.g., Brenner v. Manson, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "substantial" utility."

Finally, applicants indicated argue that they have demonstrated the polypeptide is up regulated in a marmoset cholestyramine model, which is consistent with the gene of the instant invention playing a key role in the regulation of triglyceride biosynthesis, see example 5. Applicants clearly have not identified what key role the polypeptide or the gene might play. Many acyl transferases play a role in the biosynthesis of triglycerides. Thus, the claimed invention lacks specific or substantial utility.

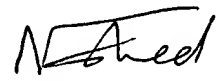
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652